

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION**

STATE OF TEXAS,

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH &
HUMAN SERVICES, et al.,

Defendants.

No. 5:24-cv-204-H

**DEFENDANTS' BRIEF IN SUPPORT OF MOTION TO DISMISS
OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT**

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INTRODUCTION

As part of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), Pub. L. 104-191, 110 Stat. 1936, Congress directed the U.S. Department of Health and Human Services (collectively with the other Defendants, the “Department”) to craft standards to protect the privacy of Americans’ sensitive medical information. To that end, in 2000, the Department promulgated a regulation, known as the Privacy Rule, restricting how such “Protected Health Information” (“PHI”) can be used and disclosed and permitting specified uses and disclosures for certain important purposes. *Standards for Privacy of Individually Identifiable Health Information*, 65 Fed. Reg. 82462-01 (Dec. 28, 2000) (codified at 45 C.F.R. pts. 160, 164) (the “2000 Privacy Rule”). In April 2024, in light of widespread concern from providers and patients about the disclosure of PHI relating to reproductive health, the Department revised the Privacy Rule to strengthen protections for PHI pertaining to lawful reproductive health care. *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32976-01 (Apr. 26, 2024) (the “2024 Rule”). The 2024 Rule has been in effect since June 25, 2024, and covered entities have generally been required to comply with the rule since December 23, 2024. *Id.*

The State of Texas now seeks to unsettle these vital privacy protections, including those in the 2000 Privacy Rule that the U.S. health care system has relied on for decades, and thereby risk the unwarranted and damaging disclosure of the private medical information of Americans nationwide. The sweeping relief that Texas requests would apply to doctor’s offices, health plans, and hospitals across the country and to medical care of all forms, whether related to reproductive health or not. Even when focused solely on the 2024 Rule, Texas’s request would decrease privacy protections for information relating to subjects as varied as contraception, prenatal care, in vitro fertilization, infertility, and menopause. The State’s request conflicts with both HIPAA and the Administrative Procedure Act and should be rejected.

As an initial matter, Texas lacks Article III standing to challenge either of the two rules at issue. The entirety of Texas's theory of harm consists of several conclusory allegations in the State's Complaint about how medical providers have occasionally invoked the rules in declining to comply with the State's requests for information. But that is not nearly enough to demonstrate injury-in-fact, particularly on summary judgment, where evidence, not boilerplate assertions of harm, is required. This case should therefore be dismissed for lack of subject-matter jurisdiction.

Even if the Court concludes that Texas has Article III standing, it should nonetheless uphold both rules, and enter judgment for the Department.

The 2000 Privacy Rule. In addition to Article III standing, Texas's challenge to the 2000 Privacy Rule falls short on another threshold ground: the statute of limitations. The 2000 Privacy Rule was promulgated twenty-four years ago. To the extent the mere invocation of the Rule by a provider is sufficient to confer standing upon the State, Texas's cause of action almost certainly "first accrue[d]" more than six years ago and is therefore time-barred. 28 U.S.C. § 2401(a). Even if the State could surmount that hurdle, its challenge to the 2000 Privacy Rule fails even to acknowledge the Department's unambiguous authority to promulgate rules concerning "the uses and disclosures of [medical] information that should be authorized or required." 42 U.S.C. § 1320d-2 note (codifying Pub. L. 104-191, title II, § 264) (Recommendations with Respect to Privacy of Certain Health Information). In exercising that authority, the Department fully explained why it chose to promulgate a test that gives weight to both the interests of law enforcement and individuals' privacy interests.

The 2024 Rule. Texas's challenge to the 2024 Rule is similarly meritless. Texas again fails to acknowledge the Department's unambiguous authority to "adopt modifications" to the 2000 Privacy Rule "as determined appropriate." *Id.* § 1320d-3(b)(1). Nothing in the statute's text

precludes the Department from electing to provide heightened protection to forms of medical information that are widely considered to carry heightened sensitivity, as it has done before. And like the 2000 Privacy Rule, the 2024 Rule does not limit the authority of state laws relating to matters like reporting child abuse or conducting public health investigations. Indeed, the 2024 Rule does not prevent a state from obtaining information related to the provision of unlawful reproductive health care at all, including forms of care that Texas has chosen to prohibit. Finally, the Department explained each of its decisions, including why it chose to prohibit disclosures related to imposing liability for lawful reproductive care and how it addressed commenters' concerns about potential compliance burdens.

For these reasons, the Court should grant the Department's motion and dismiss this case or, in the alternative, enter judgment for the Department.

BACKGROUND

I. The Health Insurance Portability and Accountability Act

HIPAA was enacted by Congress in 1996. Subtitle F of Title II, entitled "Administrative Simplification," sought to improve health care systems by "encouraging the development of a health information system through the establishment of uniform standards and requirements for the electronic transmission of certain health information." 42 U.S.C. § 1320d note (Purpose). HIPAA applies to "covered entities," which are health plans, health care clearinghouses, and health care providers who transmit any health information electronically in connection with a standard transaction under HIPAA (e.g., billing insurance electronically). *Id.* § 1320d-1.

To protect confidentiality and ensure trust in the health care system, Congress directed the Department to submit "detailed recommendations on standards with respect to the privacy of individually identifiable health information" within one year of HIPAA's enactment. *Id.* § 1320d-2 note. Congress instructed HHS to cover "at least" the following three subjects:

- (1) The rights that an individual who is a subject of individually identifiable health information should have.
- (2) The procedures that should be established for the exercise of such rights.
- (3) The uses and disclosures of such information that should be authorized or required.

Id. Congress provided that if it did not enact legislation covering these matters within three years, “the Secretary ... shall promulgate final regulations containing such standards.” *Id.*

Recognizing that unforeseen developments might warrant revisions to HIPAA’s privacy regulations, Congress also charged the Secretary to “review th[ose] standards” and “adopt modifications to the standards (including additions to the standards), as determined appropriate, but not more frequently than once every 12 months.” *Id.* § 1320d-3(b)(1).

Congress included an express preemption provision in HIPAA. That provision mandates that “a provision or requirement under [HIPAA], or a standard or implementation specification adopted under [HIPAA] ... , shall supersede any contrary provision of State law,” with limited exceptions. *Id.* § 1320d-7(a)(1). Among other things, the statute provides that the privacy regulations promulgated by the Department “shall not super[s]ede a contrary provision of State law” if the state law imposes “more stringent” requirements. *Id.* §§ 1320d-2 note, 1320d-7(a)(2)(B). The statute also includes a “public health” exception, providing that “[n]othing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.” *Id.* § 1320d-7(b).

II. The 2000 Privacy Rule

In response to Congress’s directive, the Department submitted detailed recommendations on September 11, 1997. 65 Fed. Reg. at 82470. When Congress did not enact legislation within three years, the Department, after extensive consultation with the National Committee on Vital

and Health Statistics (“NCVHS”) and federal and state law enforcement agencies, proposed and ultimately promulgated regulations in 2000 concerning medical privacy in the form of the Privacy Rule. *Id.*

In promulgating the 2000 Privacy Rule, the Department recognized the right to privacy in personal information that has historically found expression in American law and observed that “many people believe that individuals should have some right to control personal and sensitive information about themselves.” *Id.* at 82464; *see also Whalen v. Roe*, 429 U.S. 589, 599-600 (1977) (identifying “the individual interest in avoiding disclosure of personal matters,” including “matters vital to the care of their health”). The Department noted that advances in information technology “have reduced or eliminated many of the financial and logistical obstacles that previously served to protect the confidentiality of health information and the privacy interests of individuals,” 65 Fed. Reg. at 82465, and concluded that “protection of privacy must be built into the routine operations of our health care system.” *Id.* at 82467. The Department also found that medical privacy is “necessary for the effective delivery of health care, both to individuals and to populations,” because “the entire health care system is built upon the willingness of individuals to share the most intimate details of their lives with their health care providers.” *Id.*

To that end, the 2000 Privacy Rule sets out detailed standards for the use and disclosure of “protected health information” (“PHI”), which is defined as “individually identifiable health information” that is “[t]ransmitted” or “maintained” in “electronic media” or “any other form or medium.” 45 C.F.R. § 160.103. Under the Rule, PHI is generally protected from use or disclosure without an individual’s written authorization. *Id.* § 164.502(a). However, an individual’s PHI can be used and disclosed for a number of purposes, including treatment,

payment, and health care operations, without the individual's written authorization. *Id.*

§§ 164.502(a)(1)(ii), 164.506.

The 2000 Privacy Rule also permits the disclosure of PHI without the individual's written authorization to government agencies, including both federal and state agencies, in limited, clearly defined circumstances. *Id.* § 164.512. In particular, the Rule permits the disclosure of PHI for "law enforcement purposes," including where required by a "court order"; a "grand jury subpoena"; or an "administrative request for which response is required by law" (such as federal, state, territorial, or Tribal law), so long as the information sought by that request "is relevant and material to a legitimate law enforcement inquiry," the request is "specific and limited in scope," and "[d]e-identified information could not reasonably be used." *Id.* § 164.512(f)(1). The Rule also permits the disclosure of PHI where necessary for "public health activities," such as "the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions," as well as to make reports of "child abuse or neglect," *id.* § 164.512(b); where necessary to make reports of "abuse, neglect, or domestic violence," to the extent such reports are "required by law," *id.* § 164.512(c); for "health oversight activities," *id.* § 164.512(d); as required by "judicial and administrative proceedings," *id.* § 164.512(e); and where necessary "to prevent or lessen a serious and imminent threat to the health or safety of a person or the public," *id.* § 164.512(j).

III. The 2024 Rule

In April 2023, the Department proposed to amend the 2000 Privacy Rule. 88 Fed. Reg. 23506, 23506 (Apr. 17, 2023). Again after extensive consultation with NCVHS and federal and state law enforcement agencies, as well as considering approximately 25,900 comments, the Department promulgated the 2024 Rule on April 26, 2024. *See* 89 Fed. Reg. at 32978, 32991. The 2024 Rule became effective on June 25, 2024, and regulated entities generally had until

December 23, 2024, to comply with its requirements. *Id.* at 32976. However, covered entities have until February 16, 2026, to make required amendments to their Notices of Privacy Practices. *Id.* at 32976, 32979.

In the wake of *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), the Department concluded that the “changing legal landscape increases the likelihood that an individual’s PHI may be disclosed in ways that cause harm to the interests that HIPAA seeks to protect, including the trust of individuals in health care providers and the health care system.” 89 Fed. Reg. at 32978. The 2024 Rule therefore “amends provisions of the Privacy Rule to strengthen privacy protections for highly sensitive PHI about the reproductive health care of an individual, and directly advances the purposes of HIPAA by setting minimum protections for PHI and providing peace of mind that is essential to individuals’ ability to obtain lawful reproductive health care.” *Id.*

Specifically, the 2024 Rule narrowly protects sensitive information by prohibiting regulated entities from “us[ing] or disclos[ing] protected health information for any of the following activities:

- (1) To conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.
- (2) To impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.
- (3) To identify any person for any purpose described in [(1) or (2)].”

45 C.F.R. § 164.502(a)(5)(iii)(A). The Rule also contains a “[r]ule of applicability” directing that its prohibition applies only where “[t]he reproductive health care is lawful under the law of the state in which such health care is provided” or “is protected, required, or authorized by Federal

law.” *Id.* § 164.502(a)(5)(iii)(B). Finally, the Rule directs that “[t]he reproductive health care provided by another person is presumed lawful ... unless the covered entity” has “[a]ctual knowledge that the reproductive health care was not lawful” or “[f]actual information supplied by the person requesting the use or disclosure of [PHI] that demonstrates a substantial factual basis that the reproductive health care was not lawful.” *Id.* § 164.502(a)(5)(iii)(C).

“To assist in effectuating this prohibition,” 89 Fed. Reg. at 32990, the 2024 Rule also contains a requirement that a covered entity “obtain[] an attestation” from the relevant state or federal agency before it may “use[] or disclose [PHI] potentially related to reproductive health care” for the purposes of health oversight, judicial and administrative proceedings, law enforcement, and disclosures to coroners and medical examiners. 45 C.F.R. § 164.509(a). Among other things, the attestation must contain “[a] description of the information requested” and “[a] clear statement that the use or disclosure is not for a purpose” prohibited by the 2024 Rule. *Id.* § 164.509(c)(1)(i), (iv). An attestation is “[d]efective” if “[t]he covered entity ... has actual knowledge that material information in the attestation is false” or “[a] reasonable covered entity ... would not believe that the attestation” is for a permitted purpose. *Id.* § 164.509(b)(2)(iv), (v).

The 2024 Rule also explicitly preserves the 2000 Privacy Rule’s existing provisions permitting the disclosure of PHI for public health activities, including the reporting of child abuse. The Department explained that, when HIPAA was enacted, “most, if not all, states had laws that mandated reporting of child abuse or neglect to the appropriate authorities,” that Congress had already addressed such reporting in other laws, and that the term “child abuse,” as used in these statutes, “does not include activities related to reproductive health care, such as abortion.” 89 Fed. Reg. at 33004. The Department therefore clarified that a covered entity may

not “disclose PHI as part of a report of suspected child abuse based *solely* on the fact that a parent seeks reproductive health care (e.g., treatment for a sexually transmitted infection) for a child.” *Id.* As to the Privacy Rule’s provision concerning disclosures about adult abuse victims, the 2024 Rule similarly adds a “[r]ule of construction” that “[n]othing in this section shall be construed to permit disclosures prohibited by § 164.502(a)(5)(iii) when the sole basis of the report of abuse, neglect, or domestic violence is the provision or facilitation of reproductive health care.” 45 C.F.R. § 164.512(c)(3). Finally, the 2024 Rule defines “[p]ublic health as used in the terms ‘public health surveillance,’ ‘public health investigation,’ and ‘public health intervention’” to mean “population-level activities to prevent disease in and promote the health of populations,” rather than efforts to “conduct ... investigation[s]” or “impose ... liability” on individuals. *Id.* § 160.103.

IV. This Lawsuit

Texas filed this lawsuit on September 4, 2024, asserting that both the 2000 Privacy Rule and the 2024 Rule “lack statutory authority and are arbitrary and capricious.” Compl. ¶ 9, ECF No. 1. Texas alleges that both rules “significantly harm the State[’s] ... investigative abilities” because, the State claims, entities will occasionally invoke the rules in declining to comply with the state’s requests for information. *Id.* ¶ 8. Texas therefore asks the Court to “vacate and set aside the rules and enjoin the enforcement of them.” *Id.* ¶ 9. At the request of the parties, the Court entered a schedule for dispositive cross-motions to resolve this case. *See* ECF Nos 14, 15.

LEGAL STANDARD

“The burden of proof for a Rule 12(b)(1) motion to dismiss is on the party asserting jurisdiction.” *Laufer v. Mann Hosp., L.L.C.*, 996 F.3d 269, 271 (5th Cir. 2021) (quotations omitted). “Lack of subject matter jurisdiction may be found in any one of three instances: (1) the complaint alone; (2) the complaint supplemented by undisputed facts evidenced in the record; or

(3) the complaint supplemented by undisputed facts plus the court’s resolution of disputed facts.” *Ramming v. United States*, 281 F.3d 158, 161 (5th Cir. 2001). To the extent the Court has subject-matter jurisdiction, summary judgment is appropriate where “the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986).

ARGUMENT

I. The Court should dismiss this case for lack of subject-matter jurisdiction.

Texas has not met its burden to demonstrate that it has Article III standing to challenge either of the rules at issue, and so the Court lacks subject-matter jurisdiction to adjudicate its claims. “Article III of the Constitution limits federal courts’ jurisdiction” to the adjudication of “‘Cases’ and ‘Controversies.’” *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 408 (2013). “[A]n essential and unchanging part of the case-or-controversy requirement” is that plaintiffs must have “standing to invoke the authority of a federal court.” *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 (2006) (citation omitted). Standing is therefore a “threshold jurisdictional question[,]” *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 102 (1998), determining “the power of the court to entertain the suit,” *Warth v. Seldin*, 422 U.S. 490, 498 (1975).

Texas, as the party “invoking federal jurisdiction[,] bears the burden of establishing” standing. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). “While ‘general factual allegations of injury resulting from the defendant’s conduct may suffice’ at the pleadings stage,” at summary judgment, a plaintiff “must point to specific summary judgment evidence showing that it was directly affected” by the challenged action. *Texas State LULAC v. Elfant*, 52 F.4th 248, 255 n.4 (5th Cir. 2022) (quoting *ACORN v. Fowler*, 178 F.3d 350, 354 (5th Cir. 1999)); see also *Texas v. United States*, 50 F.4th 498, 513-14 (5th Cir. 2022) (“At summary judgment, [a plaintiff] can no longer rest on mere allegations, but must set forth by affidavit or other evidence

specific facts.”) (quotation omitted). Specifically, to prevail at summary judgment, Texas must present specific evidence showing that it has “(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.” *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). Moreover, because Texas is not itself “the object” of the government action it challenges, standing “is ordinarily ‘substantially more difficult’ to establish.” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 562 (1992).

Texas has not identified an injury-in-fact that is fairly traceable to either the 2000 Privacy Rule or the 2024 Rule. “To satisfy [the injury-in-fact] requirement, [a plaintiff] must plead that ‘[it] has sustained or is immediately in danger of sustaining some direct injury.’” *Abdullah v. Paxton*, 65 F.4th 204, 208 (5th Cir. 2023) (quoting *City of Los Angeles v. Lyons*, 461 U.S. 95, 101-02 (1983)). “That injury needs to be concrete and particularized, as well as actual or imminent. Importantly, it cannot be speculative, conjectural, or hypothetical.” *Id.* (quotations omitted). “The ‘actual or imminent’ requirement is satisfied only by evidence of a ‘certainly impending’ harm or a ‘substantial risk’ of harm.” *Shrimpers & Fishermen of RGV v. Texas Comm’n on Env’t Quality*, 968 F.3d 419, 424 (5th Cir. 2020) (per curiam) (quoting *Clapper*, 568 U.S. at 414 n.5). “Allegations of *possible* future injury do not satisfy the requirements of Art. III.” *E.T. v. Paxton*, 41 F.4th 709, 716 (5th Cir. 2022) (emphasis added).

Texas has failed to establish that the challenged provisions of the 2000 Privacy Rule or the 2024 Rule meaningfully constrain its ability to investigate legal violations. To the contrary, both rules expressly permit the disclosure of information to assist with law enforcement. The challenged provision of the 2000 Privacy Rule permits disclosure where “[t]he information sought is relevant and material to a legitimate law enforcement inquiry,” “[t]he request is

specific and limited in scope,” and “[d]e-identified information could not reasonably be used.” 45 C.F.R. § 164.512(f)(1)(ii)(C). Unless Texas wishes to obtain irrelevant or immaterial personal health information, it is hard to understand how those conditions could meaningfully limit the State’s investigations. Similarly, the 2024 Rule only prohibits the disclosure of information where it will be used to investigate or impose liability “for the *mere act* of seeking, obtaining, providing, or facilitating” *lawful* reproductive health care. *Id.* § 164.502(a)(5)(iii)(A), (B) (emphasis added). If Texas seeks information to conduct an investigation into reproductive health care provided in Texas that the State has chosen to prohibit and that federal law does not protect, like an unlawful abortion, the 2024 Rule poses no bar.

Indeed, Texas provides nothing more than conclusory allegations and speculation to corroborate its assertion that these rules have limited its investigative abilities. As to the 2000 Privacy Rule, the State simply claims that “covered entities in receipt of an administrative subpoena will frequently cite the rule as the reason they cannot comply with the subpoena.” Compl. ¶ 85. But if that is the case, then Texas should be able to provide evidence of specific instances in which the issue has arisen, so that the Court can assess whether the State has a real injury. For example, Texas has not identified how often it has received such responses, the reasons those entities gave for declining to comply, whether those reasons reflected the Privacy Rule’s actual requirements, whether the State was able to cure any deficiencies in its requests, or how the State’s purported inability to obtain such information has hampered its investigations. Texas’s unadorned assertions therefore would not suffice to demonstrate standing at the motion to dismiss stage, much less constitute sufficient evidence of standing at summary judgment. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (“[T]he pleading standard Rule 8 announces does not require ‘detailed factual allegations,’ but it demands more than an unadorned, the-defendant-

unlawfully-harmed-me accusation.”) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)); *Texas State LULAC*, 52 F.4th at 255 n.4 (requiring evidence at summary judgment).

Texas’s allegations concerning the 2024 Rule are even weaker. Specifically, Texas asserts that, in one instance, “a covered entity ... cited the 2024 Privacy Rule as a reason it cannot comply with Texas’s subpoena.” Compl. ¶ 88. One past refusal is insufficient to substantiate Texas’s assertions of ongoing harm, as is necessary to obtain prospective relief. *See, e.g., Summers v. Earth Island Inst.*, 555 U.S. 488, 495 (2009) (disregarding asserted prior injury “because it relates to past injury rather than imminent future injury that is sought to be enjoined”). In any event, Texas has not shown either that this one past refusal caused it to suffer an injury in fact or that the refusal is fairly traceable to the 2024 Rule. Texas does not explain whether the entity correctly concluded that Texas’s request ran afoul of the 2024 Rule’s restrictions—e.g., whether the request sought to impose liability for the mere act of obtaining lawful reproductive care—or whether the entity simply asked for additional information. That the 2024 Rule was merely “a” reason, Compl. ¶ 88, suggests that the entity may have had other concerns about the legality of Texas’s subpoena. Nor does Texas explain how the entity’s refusal to comply affected its investigations, including whether Texas was able to obtain information from other sources. Without more, it is wholly “speculative, conjectural, [and] hypothetical” whether the 2024 Rule will interfere with Texas’s investigations. *Abdullah*, 65 F.4th at 208.

For these reasons, Texas lacks standing to challenge either the 2000 Privacy Rule or the 2024 Rule, and so this case should be dismissed for lack of subject-matter jurisdiction.

II. In the alternative, the Department is entitled to judgment on Texas’s challenge to the 2000 Privacy Rule.

Even if the Court determines that Texas has Article III standing, both of the State’s challenges fail nonetheless. As to the 2000 Privacy Rule, Texas’s claims, which likely accrued

far outside the six-year statute of limitations provided by 28 U.S.C. § 2401(a), are time-barred, *see infra* § II.A; the Department had authority and, indeed, was required to promulgate the Rule after Congress failed to enact specific standards with respect to the privacy of health information, *see infra* § II.B; and the Department’s decision to promulgate a three-factor test for law-enforcement disclosures balancing the government’s interests and the individual’s privacy interests was entirely reasonable, *see infra* § II.C. The Department is therefore entitled to judgment on Texas’s claims regarding the 2000 Privacy Rule.

A. Texas’s challenge to the 2000 Privacy Rule is time-barred.

A facial challenge to a federal rule under the Administrative Procedure Act, like other civil actions against the United States, “shall be barred unless the complaint is filed within six years after the right of action first accrues.” 28 U.S.C. § 2401(a). “A right of action ‘accrues’ when the plaintiff has a ‘complete and present cause of action’—i.e., when she has the right to ‘file suit and obtain relief.’” *Corner Post, Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 603 U.S. 799, 809 (2024) (quoting *Green v. Brennan*, 578 U.S. 547, 554 (2016)). Thus, the statute of limitations begins to run when an APA plaintiff “suffers an injury from final agency action,” and thereby acquires a “complete and present cause of action.” *Id.*

To the extent Texas has standing to challenge the 2000 Privacy Rule, its challenge was filed long after the expiration of the statute of limitations. The Rule was promulgated over twenty years ago. Moreover, the gravamen of Texas’s standing theory is that “covered entities in receipt of an administrative subpoena will frequently cite the rule as the reason they cannot comply with the subpoena.” Compl. ¶ 85. To be sure, Texas has failed to plausibly allege facts or present evidence to support that theory. For present purposes, however, Texas’s allegations confirm that Texas’s challenge is untimely. Although Texas does not identify when a covered entity first cited the 2000 Privacy Rule in refusing to comply with a subpoena, it almost certainly

occurred before September 4, 2018. Indeed, to the extent covered entities “*frequently* cite the rule,” *id.* (emphasis added), they likely first did so shortly after the Rule was promulgated. But that means that the statute of limitations likely expired sometime in the late 2000s, long before Texas filed this lawsuit. Texas’s attempt to unsettle the longstanding privacy protections embodied in the 2000 Privacy Rule is therefore time-barred.

Texas might assert that the limitation period restarts every time a covered entity cites the 2000 Privacy Rule in refusing to comply, but that would be incorrect. Section 2401(a) bars complaints that are “filed within six years after the right of action *first* accrues.” (emphasis added). To the extent that a covered entity’s rejection of a State subpoena based on the Rule constitutes sufficient injury-in-fact, then Texas’s right of action accrued the *first* time a covered entity cited the Rule. *See, e.g., Herr v. U.S. Forest Serv.*, 803 F.3d 809, 822 (6th Cir. 2015) (applying rule later adopted in *Corner Post* and concluding that right of action accrues “[w]hen a party *first* becomes aggrieved by a regulation”); *Cogdell v. Reliance Standard Life Ins.*, 2024 WL 4182589, at *3 n.7 (E.D. Va. Sept. 11, 2024) (applying *Corner Post* and concluding that plaintiff’s statute of limitations ran “from the time it faced its first” source of injury). Nor would any subsequent refusal result in a new or different right of action, given that Texas’s right of action consists of a facial challenge to the 2000 Rule, rather than a challenge to any individual refusal or application of the Rule. Once the first entity rejected a State subpoena based on the Rule, Texas acquired a “complete and present cause of action,” and the clock began to run. *Corner Post*, 603 U.S. at 809. It has long since expired.

B. The Department had the authority to promulgate the 2000 Privacy Rule.

Even if Texas’s challenge to the 2000 Privacy Rule were timely, the Rule rests on unambiguous statutory authority. In enacting HIPAA, Congress directed the Secretary to recommend and, if Congress declined to act, promulgate “standards with respect to the privacy

of individually identifiable health information” including “at least ... (1) [t]he rights that an individual who is a subject of individually identifiable health information should have”; “(2) [t]he procedures that should be established for the exercise of such rights”; and “(3) [t]he uses and disclosure of such information that should be authorized or required.” 42 U.S.C. § 1320d-2 note. That specific grant of authority buttresses the Secretary’s authority to “make and publish such rules and regulations ... as may be necessary to the efficient administration of the functions with which [the Secretary] is charged.” *Id.* § 1302(a). Pursuant to these authorities, the Department promulgated the provisions of the 2000 Privacy Rule, including its three-part test for determining when a covered entity is authorized to disclose information “for law enforcement purposes,” found in subsection (f) of § 164.512.

Texas puzzlingly asserts that the 2000 Privacy Rule “cites no statutory authority supporting” subsection (f)’s three-part test. Compl. ¶ 33; *see also id.* ¶ 75. The Rule, as originally promulgated, explicitly stated that “[t]he requirements of this subchapter implement sections 1171 through 1179 of the Social Security Act (the Act), as added by section 262 of Public Law 104–191,” now codified, *inter alia*, at 42 U.S.C. §§ 1320d *et seq.*, “and section 264 of Public Law 104–191,” now found at 42 U.S.C. § 1320d-2 note. 65 Fed. Reg. at 82798 (containing 45 C.F.R. § 160.101, now codified as amended at 45 C.F.R. § 160.102); *see also* 65 Fed. Reg. at 82469-70, 82487 (discussing the Department’s authorities and responsibilities under HIPAA). Texas gives no reason why any of these explanations are inadequate, or why the Department needed to parrot the authority for the Rule in discussing each of its provisions, as opposed to at the beginning of the Rule’s regulatory text and preamble.

Instead, Texas seems to suggest that the Department lacks the authority to establish conditions for the disclosure of information to law enforcement because the statute does not

specifically address that category of disclosure. *See* Compl. ¶¶ 18, 31-32. But disclosures of information to law enforcement fall within the Department’s broad authority to regulate permissible uses and disclosures. 42 U.S.C. § 1320d-2 note. There is “no such thing as a ‘canon of donut holes,’ in which Congress’s failure to speak directly to a specific case that falls within a more general statutory rule creates a tacit exception,” *Bostock v. Clayton Cnty.*, 590 U.S. 644, 669 (2020). Texas’s reading would therefore transgress the rule that courts “may not engraft [their] own exceptions onto the statutory text.” *Henry Schein, Inc. v. Archer & White Sales, Inc.*, 586 U.S. 63, 70 (2019). The “fundamental principle of statutory interpretation that ‘absent provisions cannot be supplied by the courts’ applies not only to adding terms not found in the statute, but also to imposing limits on an agency’s discretion that are not supported by the text.” *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S. 657, 677 (2020) (quoting *Rotkiske v. Klemm*, 589 U.S. 8, 14 (2019), in turn quoting Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 94 (2012)). The statute itself does not carve out disclosures to law enforcement from the Department’s regulatory authority. Thus, “[b]y introducing a limitation not found in the statute,” Texas asks the Court “to alter, rather than to interpret,” HIPAA. *Id.*

Nor does subsection (f)’s three-part test infringe upon the limited forms of state investigative authority preserved by HIPAA. *Cf.* Compl. ¶¶ 73-74. Texas is simply incorrect that HIPAA “explicitly preserves State investigative authority” in all of its forms. *Id.* ¶ 6. To the contrary, the statute generally preempts contrary state laws and includes no general exception for law enforcement investigations. *See* 42 U.S.C. § 1320d-7.

The limited exception to preemption that Texas invokes, set forth in § 1320d-7(b), expressly applies only to certain “public health” laws. That provision specifically lists the types

of public health laws that are exempt from preemption: those “providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.” *Id.* § 1320d-7(b). The 2000 Privacy Rule expressly permits those categories of disclosures in another provision of the Rule. *See* 45 C.F.R. § 164.512(b) (“Standard: Uses and disclosures for public health activities”). Section 1320d-7(b) notably does not include general law enforcement purposes, the category covered by subsection (f). Consequently, the procedural requirements set forth in subsection (f) for law enforcement disclosures cannot run afoul of § 1320d-7(b), which does not generally exempt law enforcement purposes from preemption. In any event, even if Texas were able to rewrite § 1320d-7(b) to add a law enforcement exception, Texas has not established any way in which the test in subsection (f) “invalidate[s]” or “limit[s] the authority, power, or procedures established under” any state law related to law enforcement. 42 U.S.C. § 1320d-7. Subsection (f) simply imposes ordinary conditions on disclosure, including that the information must be “material” to an investigation, that do not meaningfully hamper a state’s law enforcement abilities and so could not conflict with § 1320d-7(b).

To the extent there is any question whether the provisions of the 2000 Privacy Rule fall within the Department’s authority, Congress’s repeated decision not to disturb those regulations would resolve it. Indeed, Congress understood in declining to promulgate standards concerning medical privacy that the Department would be required to promulgate the rules it had proposed. *See* 42 U.S.C. § 1320d-2 note. Further, in 2009, when Congress passed the Health Information Technology for Economic and Clinical Health Act, a statute that amended certain HIPAA requirements, Congress explicitly provided that “[t]he standards governing the privacy and security of individually identifiable health information promulgated by the Secretary under

sections 262(a) and 264 of the Health Insurance Portability and Accountability Act of 1996 shall remain in effect to the extent that they are consistent with this subchapter.” 42 U.S.C. § 17951. In doing so, Congress at no point suggested that the Rule’s provisions concerning disclosures to law enforcement exceeded the Department’s authority or violated § 1320d-7(b).

C. The 2000 Privacy Rule is not arbitrary and capricious.

The Department also reasonably explained its decision to promulgate subsection (f)’s three-part test for determining when a covered entity may disclose information to law enforcement. *Cf.* Compl. ¶ 80. To satisfy the arbitrary-and-capricious standard, the agency need only “articulate a satisfactory explanation for the action including a rational connection between the facts found and the choice made.” *Little Sisters of the Poor*, 591 U.S. at 682 (quotation omitted). In other words, the court “simply ensures that the agency has acted within a zone of reasonableness.” *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021).

As the Department explained, subsection (f)’s three-part test is an effort to “balance competing and legitimate interests,” namely, the “importance and legitimacy of law enforcement activities”—which the Department characterized as “beyond question”—and “individuals’ privacy interests.” 65 Fed. Reg. at 82678. The Department reasoned that, “[i]f a misperception were to develop that law enforcement had instant and pervasive access to medical records, the goals of this proposed regulation could be undermined,” because “individuals might become reluctant to seek needed care or might report inaccurately to providers to avoid revealing potentially embarrassing or incriminating information.” 64 Fed. Reg. at 59961. “In addition, popular concerns about government access to sensitive medical records might impede otherwise achievable progress toward administrative simplification.” *Id.*

In promulgating the 2000 Privacy Rule, the Department “attempt[ed] to match the level of procedural protection for privacy ... with the nature of the law enforcement need for access,

the existence of other procedural protections, and individuals' privacy interests." 65 Fed. Reg. at 82679. For example, "where access to protected health information is granted after review by an independent judicial officer (such as a court order ...), no further requirements are necessary." *Id.* In contrast, where information is disclosed "pursuant to administrative process, ... the level of existing procedural protections is lower than for judicially-approved ... disclosures." *Id.* The Department noted that, "[f]or administrative requests, an individual law enforcement official can define the scope of the request, sometimes without any review by a superior, and present it to the covered entity." 64 Fed. Reg. at 59961. The Department "therefore require[d] a greater showing, specifically, the three-part test" described in subsection (f). 65 Fed. Reg. at 82679. Although Texas acknowledges the Department's explanations and generally criticizes them as "arbitrary and capricious," *see* Compl. ¶¶ 34-35, 81, 84, it provides no reason why they are insufficient under the APA's deferential standard of review.

Moreover, the Department consulted with and gave substantial weight to the interests of federal, state, and local law enforcement. *See* 65 Fed. Reg. at 82474. The Department rejected comments that encouraged it to "prohibit disclosures of protected health information to law enforcement absent patient consent," which the Department concluded "would unduly jeopardize public safety." *Id.* at 82682. The Department also declined to make the test more stringent because "law enforcement's ability to protect the public interest could be unduly compromised." *Id.* at 82683. Ultimately, Texas's arguments boil down to a disagreement with how the Department balanced the interests of law enforcement with individuals' privacy interests, but neither the State nor the Court may "substitute its own policy judgment for that of the agency." *Prometheus Radio Project*, 592 U.S. at 423. The 2000 Privacy Rule should therefore be upheld.

III. The Department is also entitled to judgment on Texas’s challenge to the 2024 Rule.

Texas’s challenge to the 2024 Rule also fails. The Department had authority to amend the 2000 Privacy Rule to account for the heightened sensitivity of reproductive health information, *see infra* § III.A., and it explained all of its decisions in promulgating the 2024 Rule, *see infra* § III.B. The Department is therefore entitled to judgment on Texas’s claims regarding the 2024 Rule as well.

A. The Department had the authority to promulgate the 2024 Rule.

The 2024 Rule is a lawful exercise of the Department’s statutory authority to revise its standards for the privacy of protected health information. *Cf.* Compl. ¶ 76. Congress not only directed the Secretary to promulgate “standards with respect to ... [t]he uses and disclosure of [PHI] that should be authorized or required,” 42 U.S.C. § 1320d-2 note; it also charged the Secretary to “review th[ose] standards” and “adopt modifications to the standards (including additions to the standards), as determined appropriate,” *id.* § 1320d-3(b)(1); *see also id.* § 1302(a) (general grant of rulemaking authority). The 2024 Rule falls well within these authorities, which the Rule fully cited and discussed. *See* 89 Fed. Reg. at 32980-84. Although Texas blithely asserts that the Department “cannot” and “does not” point to a specific source of authority, Compl. ¶ 76, it again fails to provide any reason why these authorities are inadequate.

To the extent Texas means to suggest that the Department cannot establish heightened protections for specific categories of protected health information, that is incorrect. Nothing in HIPAA’s text requires the Department to impose the same protections for all forms of health information, regardless of their sensitivity. The statute simply directs the Secretary to promulgate “standards with respect to the privacy of individually identifiable health information,” including standards regarding “uses and disclosures.” 42 U.S.C. § 1320d-2 note. If anything, Congress’s instruction that the Secretary formulate “*detailed* recommendations,” *id.* (emphasis added),

reflects Congress’s awareness that the work of standard-setting would involve significant complexity and variation. Reading the statute to preclude category-specific protections would again run afoul of the rule that neither litigants nor courts may “engraft [their] own exceptions onto the statutory text.” *Archer & White Sales*, 586 U.S. at 70.

Indeed, the Department’s regulations have long provided “special protection[]” for a specific category of records: “psychotherapy notes, owing in part to the particularly sensitive information those notes contain.” 89 Fed. Reg. at 32977-78, 32986-87 (citing 45 C.F.R. §§ 164.501, 164.508(a)(2)); *see* 65 Fed. Reg. at 82497, 82514-15; 64 Fed. Reg. at 59941-42. The Secretary’s original recommendations specifically noted that “Federal and State laws already provide stronger protections for certain information[] (such as information about HIV status, substance abuse patient information, and mental health records),” and “recognize[d] that additional types of particularly sensitive information may be identified for special protection in the future.” *Recommendations of the Secretary of Health and Human Services*, U.S. Dep’t of Health & Hum. Servs. (Sep. 10, 1997), <https://perma.cc/FQ4S-Y45C>. NCVHS, the public advisory body to the Secretary with which the Department is statutorily required to consult, *see* 42 U.S.C. § 1320d-2 note, has also repeatedly recommended that the Department strengthen protections for particular categories of information, *see* 89 Fed. Reg. at 32986-87. The 2024 Rule therefore falls well within how the Department’s authority to promulgate regulations concerning permissible uses and disclosures has long been understood.

For the same reasons, the 2024 Rule does not run afoul of the major questions doctrine. Rules concerning when private medical information can be disclosed do not involve a controversy of great “economic and political significance,” nor is the 2024 Rule “transformative,” a “radical or fundamental change,” or a “wholesale restructuring” of the

Department’s authority under HIPAA. *West Virginia v. EPA*, 597 U.S. 697, 716, 720-24 (2022). Moreover, this is not a circumstance where the agency has discovered “newfound power in the vague language of an ancillary provision of [an] Act.” *Id.* at 724 (quotation omitted). The 2024 Rule’s disclosure prohibition is an exercise of the Department’s core authority under HIPAA to promulgate rules concerning permissible “uses and disclosures” of PHI, 42 U.S.C. § 1320d-2 note, and to adopt appropriate modifications to those rules, *id.* § 1320d-3(b)(1), as the Department has done for decades. Thus, the 2024 Rule “is neither novel nor unprecedented.” *Strickland v. USDA*, 2024 WL 2886574, at *4-5 (N.D. Tex. 2024).

Like the 2000 Privacy Rule, the 2024 Rule also does not infringe upon the limited public health authorities preserved by § 1320d-7(b). *Cf.* Compl. ¶¶ 73-74. To reiterate, § 1320d-7(b) does not provide blanket immunity for all law-enforcement related activities from HIPAA’s requirements and protections—it carves out a limited subset of public health-related activities. *See supra* pages 17-18. The 2024 Rule does not alter the provision of the 2000 Privacy Rule that permits the use or disclosure of information for those activities. *See* 45 C.F.R. § 164.512(b). Moreover, the 2024 Rule’s disclosure prohibition—and its related presumptions and attestation requirement—applies only to disclosures aimed at investigating or imposing liability for the mere act of seeking or facilitating lawful reproductive health care, and expressly does not apply to the public-health disclosure provision. *See id.* §§ 164.502(a)(iii), 164.509(a). Thus, the Rule in no way “limit[s] the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.” 42 U.S.C. § 1320d-7(b). And to the extent it could be construed to do so, the proper remedy would be to enjoin the Department from enforcing the

Rule with respect to reports covered by § 1320d-7(b) when made in compliance with the requirements of state law. *See* 45 C.F.R. § 164.535 (severability provision).

B. The 2024 Rule is not arbitrary and capricious.

The Department also acted well “within a zone of reasonableness,” *Prometheus Radio Project*, 592 U.S. at 423, in promulgating the 2024 Rule’s disclosure restrictions. None of Texas’s objections to the Department’s explanations pass muster.

1. To start, the Department fully explained why it chose to adopt the prohibitions on disclosure in the 2024 Rule. *Cf.* Compl. ¶ 81. The Department found that “th[e] changing legal landscape increases the likelihood that an individual’s PHI may be disclosed in ways that cause harm to the interests that HIPAA seeks to protect, including the trust of individuals in health care providers and the health care system.” 89 Fed. Reg. at 32978. The 2024 Rule therefore “amends provisions of the Privacy Rule to strengthen privacy protections for highly sensitive PHI about the reproductive health care of an individual, and directly advances the purposes of HIPAA by setting minimum protections for PHI and providing peace of mind that is essential to individuals’ ability to obtain lawful reproductive health care.” *Id.*; *see also id.* at 32984-91. The Department did not seek “to obstruct States’ ability to enforce their own laws on abortion” or other forms of care, Compl. ¶ 39; to the contrary, it made plain that the 2024 Rule’s prohibitions do not apply to investigations into forms of care that are unlawful. *See* 45 C.F.R. § 164.502(a)(5)(iii)(B); 89 Fed. Reg. at 33012-13.

The Department also explained why it adopted a broad definition of reproductive health care for the purpose of applying the 2024 Rule’s prohibitions. *Cf.* Compl. ¶¶ 40-41. The Department did so because it sought to “encompass[] the full range of health care related to an individual’s reproductive health.” 89 Fed. Reg. at 33005. That “approach is consistent with the approach the Department took when it adopted the definition of ‘health care’ in the HIPAA

Rules,” which was framed broadly to avoid “the risk that important activities would be left out,” creating “confusion.” *Id.* The Department also reasoned that a broad definition “may decrease the perceived burden to regulated entities of complying with the rule by helping them determine whether a request for the use or disclosure of PHI includes PHI that is implicated by this final rule.” *Id.* at 33005-06. Although Texas generally objects to the definition the Department chose, the State offers no explanation for why it thinks a broad definition is unlawful, nor does it identify an alternative definition of reproductive health care that it believes the Department should have adopted.

Texas objects to the fact that covered entities may disclose PHI to defend against a claim or prosecution, *see* Compl. ¶¶ 43-44, but the State’s argument relies on a misinterpretation of the 2024 Rule. The 2000 Privacy Rule has long permitted entities to make certain disclosures to obtain legal services or for the purposes of legal proceedings. 45 C.F.R. §§ 164.501 (definition of “health care operations”), 164.502(a)(1)(ii), 164.506(c)(1), 164.512(e). The quoted language from the 2024 Rule’s preamble does not expand these permissions, but instead describes a change from the proposed rule to the final rule designed to avoid a construction of the 2024 Rule that might *limit* those permissions. *See* 89 Fed. Reg. at 33010-11. Moreover, the 2024 Rule does not prohibit the disclosure of PHI in connection with the unlawful provision of care at all, so such information may be disclosed by an entity whether for the purpose of defending against a claim or pursuant to an otherwise-valid request from law enforcement. *See* 45 C.F.R. § 164.502(a)(5)(iii)(B). In any event, Texas never explains why a purported lack of symmetry between the 2024 Rule’s disclosure provisions has any bearing on their lawfulness.

2. Next, the Department explained why the 2024 Rule permits providers to presume that reproductive health care provided by another entity is lawful. *Cf.* Compl. ¶ 82. The

Department adopted the presumption in response to “commenters’ concerns” about the “workability” of requiring entities to determine whether care provided by another is lawful, given that an entity “may not have access to all of the relevant information, including medical records with the necessary information, to determine whether prior reproductive health care obtained by an individual was lawful.” 89 Fed. Reg. at 33014-15. To the extent Texas is concerned that the presumption might limit its ability to obtain information, *see* Compl. ¶¶ 49-54, the presumption can be overcome if the entity has “[a]ctual knowledge that the reproductive health care was not lawful” or “[f]actual information supplied by the person requesting the use or disclosure ... that demonstrates a substantial factual basis that the reproductive health care was not lawful.” 45 C.F.R. § 164.502(a)(5)(iii)(C). Texas never explains why providing information to substantiate its belief that a given instance of care was unlawful would somehow be onerous or infeasible. Instead, the State appears to insist that it should be able to obtain private health information whenever it wants.

3. Finally, the Department explained the 2024 Rule’s attestation requirement. *Cf.* Compl. ¶ 83. The Department recognized that “it may be difficult for regulated entities to distinguish between requests for the use and disclosure of PHI based on whether the request is for a permitted or prohibited purpose, which could lead regulated entities to deny use or disclosure requests for permitted purposes.” 89 Fed. Reg. at 33029. The attestation provision therefore requires a requester who seeks information potentially related to reproductive health care to provide certain forms of information to the entity, so that the entity can determine whether the request is for a prohibited purpose. *See id.* at 33030; 45 C.F.R. § 164.509(a)(1). The Department specifically declined to extend the attestation requirement to requests that do not involve PHI related to reproductive health care to avoid undue interference with law

enforcement. *See* 89 Fed. Reg. at 33029. The Department also thoroughly addressed comments regarding the attestation requirement, *see id.* at 33032-42, and even provided a model attestation and multiple other resources (including fact sheets, compliance videos, model presentation webinars, and slides) to make it easier for parties to apply the Rule’s requirements. *See, e.g., Model Attestation*, HHS, <https://www.hhs.gov/sites/default/files/model-attestation.pdf>; *HIPAA and Reproductive Health*, HHS, <https://www.hhs.gov/hipaa/for-professionals/special-topics/reproductive-health/index.html>.¹

In sum, Texas has not identified any aspect of the 2024 Rule (or the 2000 Rule) that the Department failed to reasonably explain. The State may disagree with the Department’s explanations and policy choices, but that is not nearly enough to prevail on an arbitrary-and-capricious challenge.

IV. Any relief should be limited to the State of Texas and to the specific provisions the Court concludes are unlawful and harmful.

The Court should enter judgment for the Department. But if it enters judgment for Texas, it should not grant the extraordinarily sweeping relief that the State seeks. Texas requests that the Court “[v]acate and set aside the 2000 Privacy Rule and the 2024 Privacy Rule,” presumably in their entirety, “and permanently enjoin Defendants from enforcing them.” Compl., Demand for Relief ¶ c; *see id.* ¶ 9. In addition to unsettling privacy protections that have safeguarded the confidentiality of Americans’ health information for decades, Texas’s request for universal relief would transgress basic principles of jurisdiction, equity, and judicial review under the APA.

¹ Texas is also incorrect to suggest that an entity that “guess[es] wrong about the validity of an attestation ... is subject to criminal liability.” Compl. ¶ 63; *see id.* ¶¶ 5, 17. A provider cannot be held criminally liable unless it “knowingly and in violation of” HIPAA discloses PHI. 42 U.S.C. § 1320d-6.

As an initial matter, the APA’s provision for courts to “set aside” unlawful agency actions, 5 U.S.C. § 706(2), does not authorize the type of universal vacatur that Plaintiff seeks. As a matter of first principles, the “set aside” language in § 706(2) should not be read as authorizing remedies, which are governed by § 703 of the APA. Section 703 states that “[t]he form of proceeding for judicial review” of agency action is either a “special statutory review proceeding” or, in “the absence or inadequacy thereof,” any “applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus.” 5 U.S.C. § 703. Because Plaintiff does not purport to identify any applicable “special statutory review proceeding,” § 703 affords it only traditional equitable remedies like injunctions. In contrast, § 706(2) does not address remedies at all. Rather, § 706(2) is properly understood as a rule of decision directing the reviewing court to disregard unlawful “agency action, findings, and conclusions” in resolving the case before it, consistent with basic principles of judicial review. Universal vacatur is therefore not an available remedy under the APA. *See United States v. Texas*, 599 U.S. 670, 693-99 (2023) (Gorsuch, J., concurring in the judgment).

Defendants recognize that the Fifth Circuit has held that the “APA ‘empowers and commands courts to set aside unlawful agency actions,’ allowing a district court’s vacatur to render a challenged agency action ‘void.’” *Texas Med. Ass’n v. U.S. Dep’t of Health & Hum. Servs.*, 110 F.4th 762, 779 (5th Cir. 2024) (internal citation omitted). Defendants nevertheless preserve the argument that vacatur is not a permissible remedy under the APA for the purposes of appeal. Even assuming that vacatur is permissible, however, the APA does not require courts to vacate federal rules. *See Staley v. Harris Cnty.*, 485 F.3d 305, 310 (5th Cir. 2007) (“[V]acatur is to be determined on a case-by-case basis, governed by facts and not inflexible rules.”). As the Fifth Circuit has held, whether vacatur is appropriate depends on “the seriousness of the

deficiencies of the action” and “the disruptive consequences of vacatur.” *Texas v. Biden*, 20 F.4th 928, 1000 (5th Cir. 2021). Here, as described above, both the 2000 Privacy Rule and the 2024 Rule are lawful. And to the extent that the Court concludes that the Department failed to adequately explain its decisions in promulgating either of the two rules at issue, those errors could be rectified on remand to the agency. *See id.*

Vacatur of these rules would also be deeply disruptive to the public’s interest in the privacy of medical information. As the Department has repeatedly recognized, medical information is considered sensitive by many, and “[i]nformation about reproductive health care is particularly sensitive and requires heightened privacy protection.” 89 Fed. Reg. at 32990; *see also id.* at 32986-87 (citing AMA’s Principles of Medical Ethics and recommendations of NCVHS). “Many people believe that details about their physical self should not generally be put on display for neighbors, employers, and government officials to see.” 65 Fed. Reg. at 82464. Indeed, “[i]nvoluntary or poorly-timed disclosures can irreparably harm relationships and reputations, and even result in job loss or other negative consequences in the workplace.” 89 Fed. Reg. at 33057. Although vacating either the 2000 Privacy Rule or the 2024 Rule would harm the public’s interest in privacy, vacating the 2000 Privacy Rule would particularly unsettle longstanding expectations of confidentiality.

Setting these rules aside would also reduce the trust that individuals have in the medical system, reducing the likelihood that they will seek or receive appropriate care. “[I]ndividuals may be deterred from seeking needed health care if they do not trust that their sensitive information will be kept private.” 89 Fed. Reg. at 32984; *see* 88 Fed. Reg. at 23508 & nn.12-16 (citing studies); 65 Fed. Reg. at 82468 (same); *Whalen*, 429 U.S. at 602 (“Unquestionably, some individuals’ concern for their own privacy may lead them to avoid or to postpone needed

medical attention.”). Other patients may seek care but withhold information from their providers, depriving providers of “necessary information ... for an appropriate treatment plan, which may result in negative health outcomes at both the individual and population level.” 89 Fed. Reg. at 32991. And even when a provider receives accurate information, the provider may “leave gaps or include inaccuracies when preparing medical records, creating a risk that ongoing or future health care could be compromised.” *Id.* at 32985. Given these potential nationwide harms, universal vacatur would be unwarranted.

The Court also has equitable alternatives to vacatur. Rather than vacate either of the two rules nationwide, the Court could simply enjoin the Department from applying those rules within the State of Texas, leaving Texas free to obtain sensitive identifiable information from medical providers within the State, without restriction. In contrast, the problems caused by overbroad universal remedies are well catalogued and apply whether such a remedy takes the form of a universal vacatur or a nationwide injunction. “[S]tanding is not dispensed in gross”: A plaintiff’s remedy must be tailored to redress the plaintiff’s particular injury.” *Gill v. Whitford*, 585 U.S. 48, 73 (2018) (quoting *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 353 (2006)). Moreover, “injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs.” *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979). However framed, universal relief also threatens to “stymie the orderly review of important questions,” “render meaningless rules about joinder and class actions,” and “sweep up nonparties who may not wish to receive the benefit of the court’s decision.” *United States v. Texas*, 599 U.S. 670, 703 (2023) (Gorsuch, J., concurring, joined by Thomas & Barrett, JJ.).

Whatever remedy the Court enters, it should also tailor any relief in light of the severability provision contained in HIPAA’s implementing regulations. That provision directs

that, “[i]f any provision of the [2024 Rule] is held to be invalid or unenforceable facially, or as applied to any person, plaintiff, or circumstance, it shall be construed to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which case the provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other dissimilar circumstances.” 45 C.F.R. § 164.535. As to the 2000 Rule, the Rule’s conditions regarding disclosures for law enforcement purposes can easily be severed, if necessary, from the remainder of the Rule. And, as to the 2024 Rule, the Department explained in the preamble that it “intends that, if a specific regulatory provision in this rule is found to be invalid or unenforceable, the remaining provisions of the rule will remain in effect because they would still function sensibly.” 89 Fed. Reg. 33048. Invalidating provisions of these rules other than those specifically held to be unlawful would unnecessarily jeopardize safeguards that are vital to the protection of Americans’ sensitive medical information.

CONCLUSION

For these reasons, the Court should grant the Department’s motion and dismiss this case or, in the alternative, enter judgment for the Department.

Dated: January 17, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 17, 2025, a copy of the foregoing was filed electronically via the Court's ECF system, which effects service upon counsel of record.

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